NOV 2 7 2002

Adapters with X-Coating

Submitter Information:

Name and Address:
Terumo Cardiovascular Systems Corporation
28 Howe Street
Ashland, MA 01721

Contact Person:
Kazuhito Inoue
Terumo Cardivascular Systems Corporation
125 Blue Ball Road
Elkton, MD 21921
Telephone: 1-800-283-7866, Ext. 7001

Date of Preparation: September 3, 2002

Device Names:

Proprietary Name:	Adapters with X-Coating
Common Name:	Adapters
Classification Name:	Adapter, Stopcock, Manifold, Fitting Cardiopulmonary Bypass

Predicate Device:

The Adapters with X-Coating that are the subject of this premarket notification are substantially equivalent to the predicate devices, the uncoated adapters, which are legally marketed and have been in interstate commerce prior to May 28, 1976. As such, the predicate adapters are considered to have *preamendment* status.

Intended Use:

The Adapters with X-Coating are intended to be used to interconnect tubing and other devices within a circuit during extracorporeal bypass procedures.

The adapters are intended for use in procedures lasting up to 6-hours in duration.

The blood-contacting surfaces of the adapters are coated with X-Coating, which is a biocompatible coating that reduces the adhesion of platelets to the surfaces.

Principles of Operation and Technology:
The adapters that are the subject of this premarket notification perform by providing a connection between devices within a bypass circuit, effectively establishing a conduit between the devices for the flow of blood and other extracorporeal fluids.

Design and Materials:
The Adapters with X-Coating are of various designs (Male luer lock adapters, Female luer lock adapters, Needle/Slip adapters, Straight adapters, Y-adapters), each of which provide for the flow of blood and extracorporeal fluids through the bypass circuit. Each adapter is molded from polycarbonate or acrylic resin.

Performance Evaluations:
The performance of the Adapters with X-Coating submitted in this premarket notification is substantially equivalent to the performance of the uncoated adapters. The following tests were conducted to demonstrate equivalence in performance:

- Dimensional/Visual Analysis
- Leakage and Mechanical Integrity Testing
- Pull Force Testing (Against Tubing)
- 6-hour Circulation Testing
  - Damage
  - Thrombus formation (Visual)

Substantial Equivalence Comparison:
The Adapters with X-Coating are substantially equivalent to the uncoated adapters as follows:

- Intended Use: The Adapters with X-Coating and the uncoated adapters are intended to be used to interconnect tubing and other devices within a circuit during extracorporeal bypass procedures. Both are intended to be used during procedures lasting up to 6 hours duration.

- Principles of Operation and Technology: The Adapters with X-Coating and the uncoated adapters each utilize the same technologies in the operation of the devices. The adapters provide a connection between devices within a bypass circuit, effectively establishing a conduit between the devices for the flow of blood and other extracorporeal fluids.

- Design and Materials: The design and the materials of the Adapters with X-Coating and the uncoated adapters are exactly the same with the exception of the X-Coating polymer that is applied to the coated adapters.

- Performance: Comparisons of the performance of the Adapters with X-Coating and the uncoated adapters were conducted. The comparisons demonstrated that there were no clinically significant performance differences between the coated and uncoated devices.

Substantial Equivalence Summary:

In summary, the Adapters with X-Coating and the uncoated adapters are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance. Any noted differences between the two devices do not raise new issues of safety and effectiveness.

Additional Safety Information:

- Sterilization conditions have been validated in accordance with AAMI guidelines to provide a Sterility Assurance Level (SAL) of 10^{-6}.

- Ethylene Oxide residues will not exceed the maximum residue limits proposed for Part 821 of Title 21 in the Federal Register of June 23, 1978 (or as finalized or amended).

- Terumo Cardiovascular Systems Corporation conducted biocompatibility studies as recommended in the FDA General Program Memorandum #G95-1 (5/1/95): Use of International Standard ISO 10993, "Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing." [External Communicating Devices, Circulating Blood, Limited Exposure (≤ 24 hours) Contact Duration]. The blood contacting materials were found to be biocompatible.

- The polymer coating material that is applied to the blood-contacting surfaces of the device was also evaluated in an *in-vivo* animal study. No adverse conditions were noted.

Conclusion:

In summary, the Adapters with X-Coating are substantially equivalent in intended use, principles of operation and technology, design and materials, and performance to the uncoated adapters which have preamendment status (i.e., legally marketed and in interstate commerce prior to May 28, 1976).

Terumo Cardiovascular Systems Corporation's statement that these devices are substantially equivalent to any other devices is done solely to comply with the requirements of the Federal Food, Drug and Cosmetic Act and is not intended to be the basis for patent infringement action.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 7 2002

Terumo Cardiovascular Systems Corp.
c/o Mr. Kazuhito Inoue
125 Blue Ball Road
Elkton, MD 21921

Re: K022918
Adapters with X-Coating
Regulation Number: 870.4290
Regulation Name: Cardiopulmonary Bypass Adaptor, Stopcock, Manifold, or Fitting
Regulatory Class: Class II (two)
Product Code: DTL
Dated: September 3, 2002
Received: September 4, 2002

Dear Mr. Inoue:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman. M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K022918

Device Name: **Adapters with X-Coating**

Indications For Use:

Intended Use Described In The 510(k):

The Adapters with X-Coating are intended to be used to interconnect tubing and other devices within a circuit during extracorporeal bypass procedures.

The adapters are intended for use in procedures lasting up to 6-hours in duration.

The blood-contacting surfaces of the adapters are coated with X-Coating, which is a biocompatible coating that reduces the adhesion of platelets to the surfaces.

Kazuhito Inoue

Kazuhito Inoue
Regulatory Affairs
Terumo Cardiovascular Systems Corp.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

Division of Cardiovascular & Respiratory Devices
510(k) Number K022918